

JNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/521,086 03/07/00 LAZAROV М 11699-002001 **EXAMINER** IM52/0620 Gilbert H Hennessey PAULRAJ, C Fish & Richardson PC **ART UNIT** PAPER NUMBER 225 Franklin Street Boston MA 02110-2804 1773 **DATE MAILED:**

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary		Application No.	Applicant(s)
		09/521,086	LAZAROV ET AL.
		Examiner	Art Unit
		Christopher G. Paulraj	1773
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status			
1)🛛	Responsive to communication(s) filed on 211	<u>May 2001</u> .	
2a) <u></u> □	This action is FINAL . 2b)⊠ Th	nis action is non-final.	
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims			
4)⊠ Claim(s) <u>1-19</u> is/are pending in the application.			
4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.			
5)	Claim(s) is/are allowed.		
6)⊠)⊠ Claim(s) <u>1-3 and 17-19</u> is/are rejected.		
7) 🖾	Claim(s) <u>4-11</u> is/are objected to.		
8) Claims 1-19 are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10)[0) The drawing(s) filed on is/are objected to by the Examiner.		
11)	The proposed drawing correction filed on	_ is: a)□ approved b)□ disapp	proved.
12)	The oath or declaration is objected to by the E	xaminer.	
Priority under 35 U.S.C. \$ 119			
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. \$ 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of:			
1. Certified copies of the priority documents have been received.			
2. Certified copies of the priority documents have been received in Application No			
3. Copies of the certified copies of the priority documents have been received in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.			
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).			
Attachment(s)			
15) Noti 16) Noti	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449) Paper No(s)	19) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 1-11 and 17-19 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that a full search of the elected Group I claims should in fact cover the same ground needed to be covered in connection with method claim 12. This is not found persuasive because the method claims require that the metal layer is applied at a temperature of 20 to 500 °C under vacuum. There is no such requirement in the product claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Claim Objections

Claims 4-11, 1/17, and 19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 101/112

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Claims 17-19 provide for the use of an article for implantation, insertion, or attachment, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson (U.S. Patent 5,496,359).

Davidson discloses zirconium oxide and zirconium nitride coated biocompatible leads in which the coating is applied by physical or chemical vapor deposition (abstract). The coated surfaces may be further coated with other compositions such as heparin and protein to further enhance biocompatibility (col. 4, lines 20-25).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buechel et al. (U.S. patent 5,868,796) in view of Davidson (U.S. Patent 5,496,359).

Buechel et al. discloses prosthesis with a biologically inert wear resistant surface which is coated with a biologically inert coating medium such a titanium nitride (abstract, col. 5, lines 15-16). One skilled in the art would have found it obvious to coat the surface of such an article with biocompatibility enhancing agents such as proteins and heparins in a manner similar to that disclosed by Davidson. The motivation for doing so would have been to enhance the biocompatibility of the prosthesis.

Information Disclosure Statement

Receipt of Information Disclosure Statement filed on May 21, 2001 is acknowledged and has been made of record. Foreign language documents were only considered to the extent of what their English abstracts provided.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher G. Paulraj whose telephone number is (703) 308-1036. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on (703) 308-1261. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7718 for regular communications and (703) 305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0661.

cgp June 18, 2001

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